IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA

CHARLESTON DIVISION

TERRESKI MULLINS, et al.,

Plaintiffs,

v. CIVIL ACTION NO. 2:12-cv-02952

ETHICON, INC., et al.,

Defendants.

MEMORANDUM OPINION AND ORDER

Pending before the court is the defendants' Motion for Summary Judgment on Design Defect [ECF No. 128], in which they argue that the plaintiffs' claims are preempted by federal law. For the reasons set forth below, the motion is **DENIED**.

I. Background

This case represents the consolidation of 37 out of nearly 23,000 cases filed against Ethicon Inc. and Johnson & Johnson (collectively "Ethicon"). The Ethicon MDL is one of seven MDLs assigned to me related to pelvic mesh, collectively encompassing nearly 70,000 cases. This action involves 37 West Virginia plaintiffs who were implanted with Tension-free Vaginal Tape ("TVT"), a mesh product manufactured by Ethicon to treat stress urinary incontinence ("SUI"). These cases have been consolidated on the defective design element of the plaintiffs' negligent design and strict liability design defect claims. *See* PTO No. 184 [ECF No. 25].

In the instant motion, Ethicon moves for summary judgment, arguing that the plaintiffs' claims for strict liability design defect and negligent design defect "conflict with, and so are

preempted by, federal law." Mem. Supp. Defs.' Mot. Summ. J. 1 [ECF No. 129]. Their argument rests on a theory of implied conflict preemption, specifically impossibility preemption. This will be the fourth time in the course of this MDL that I have considered Ethicon's arguments that the plaintiffs' state law claims are preempted by the FDA's 510(k) premarket clearance process. I have determined each time that the plaintiffs' claims are not preempted, relying on Supreme Court precedent in *Medtronic v. Lohr*, 518 U.S. 470 (1996). *See, e.g., Bellew v. Ethicon Inc.*, No. 2:13-cv-22473, 2014 WL 6674424 (S.D. W. Va. Nov. 24, 2014) (finding that the plaintiffs' claims are not preempted by federal law). In *Lohr*, the Court held that the 510(k) clearance process—which is rooted in a determination of "substantial equivalence" rather than safety and effectiveness—does not preempt state-law design defect claims. *Id.* at 493–94. The defendants have now adjusted their theory in order to present what they believe is an "issue of first impression in this litigation." Mem. Supp. Defs.' Mot. Summ. J. 1.

The defendants argue that *Lohr* neither considered nor precluded the applicability of implied conflict preemption. Thus, the issue before me is whether analyzing the 510(k) clearance process under a newly minted version of impossibility conflict preemption, rather than express preemption, will require a different outcome. I find that it does not. The plaintiffs' state law design defect claims are not preempted by the federal 510(k) clearance process.

II. Federal Preemption

Federal preemption is rooted in the Supremacy Clause, which provides that "[t]his Constitution, and the Laws of the United States which shall be made in Pursuance thereof . . . shall be the supreme Law of the Land . . . any Thing in the Constitution or Laws of any State to the Contrary notwithstanding." U.S. Const. art. VI, cl. 2. Consequently, Congress may preempt—or

invalidate—a state law. *Oneok, Inc. v. Learjet, Inc.*, 135 S. Ct. 1591, 1595 (2015). Preemption may be express, through language in a statute, or implied. *See id.* ("[E]ven where . . . a statute does not refer expressly to pre-emption, Congress may implicitly pre-empt a state law, rule, or other state action."). There are two types of implied preemption: field preemption and conflict preemption. *Id.* Conflict preemption exists where the state law "stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress" or where "compliance with both state and federal law is impossible." *Id.* (quoting *California v. ARC Am. Corp.*, 490 U.S. 93, 100–101 (1989)). The latter is known as impossibility preemption and is usually described in terms of physical impossibility. *See, e.g.*, *Arizona v. United States*, 132 S. Ct. 2492, 2501 (2012) ("[S]tate laws are preempted when they conflict with federal law. This includes cases where 'compliance with both federal and state regulations is a physical impossibility . . . .'"(citations omitted) (quoting *Fla. Lime & Avocado Growers, Inc. v. Paul*, 373 U.S. 132, 142–43 (1963))). Consequently, "[i]mpossibility pre-emption is a demanding defense." *Wyeth v. Levine*, 555 U.S. 555, 573 (2009).

Two related principles guide preemption analysis: the general presumption against preemption and the purpose of Congress. *Id.* at 565. First, when analyzing questions of express or implied preemption, "courts should assume that 'the historic police powers of the States' are not superseded 'unless that was the clear and manifest purpose of Congress.'" *Arizona*, 132 S. Ct. at 2501 (quoting *Rice v. Santa Fe Elevator Corp.*, 331 U.S. 218, 230 (1947)). Second, the Supreme Court has repeatedly stated that "the purpose of Congress is the ultimate touchstone in every pre-emption case." *E.g.*, *Wyeth*, 555 U.S. at 565 (quoting *Lohr*, 518 U.S. at 485). "Evidence of pre-emptive purpose is sought in the text and structure of the statute at issue." *CSX Transp., Inc. v. Easterwood*, 507 U.S. 658, 664 (1993). "If the statute contains an express pre-emption clause, the

task of statutory construction must in the first instance focus on the plain wording of the clause, which necessarily contains the best evidence of Congress' pre-emptive intent." *Id*; *see also Sprietsma v. Mercury Marine*, 537 U.S. 51, 61–68 (2002) (addressing both express and implied preemption arguments).

III. Defendants' Argument

The defendants conceptualize impossibility conflict preemption as applying "wherever state law requires a defendant to do something that it cannot do *independently* under federal law," or stated differently, "a state cannot require a manufacturer to make a change in its product if it would be impossible to make that change without the permission of the federal government." Mem. Supp. Defs.' Mot. Summ. J. 1–2. The defendants derive this proposition from recent Supreme Court cases that address conflict preemption in the context of FDA-approved drug labeling. In *Wyeth v. Levine*, 555 U.S. 555 (2009), the Court found no impossibility preemption for brand-name drug manufacturers because the manufacturer could "do *unilaterally* what state law requires." Mem. Supp. Defs.' Mot. Summ. J. 3 (citing *Wyeth*, 555 U.S. at 572–73). Conversely, in *PLIVA, Inc. v. Mensing*, 131 S. Ct. 2567 (2011), the Court found preemption for generic drug manufacturers because the generic manufacturer could not take unilateral action to bring its labeling into compliance with state duties:

> To decide these cases, it is enough to hold that when a party cannot satisfy its state duties without the Federal Government's special permission and assistance, which is dependent on the exercise of judgment by a federal agency, that party cannot independently satisfy those state duties for pre-emption purposes.

Mensing, 131 S. Ct. at 2580–81; Mem. Supp. Defs.' Mot. Summ. J. 3. In *Mutual Pharmaceutical Co. v. Bartlett*, 133 S. Ct. 2466 (2013), the Court applied *Mensing* and again found preemption for generic drug manufacturers because "federal law prevents generic drug manufacturers from

changing their labels." *Id.* at 2476. The defendants use *Bartlett* for the proposition that a defendant cannot avoid a conflict for preemption purposes by "choosing to 'stop selling' an allegedly defective product." Mem. Supp. Defs.' Mot. Summ. J. 10 (citing *Bartlett*, 133 S. Ct. at 2477–78).

In the defendants' view, any success by the plaintiffs would force the defendants to stop selling their products or to make significant changes to the product's design. To make significant changes to the product's design, so the argument goes, the defendants would be required to obtain 510(k) clearance. Mem. Supp. Defs.' Mot. Summ. J. 6. Because the design changes may require FDA clearance—which the defendants equate to *Mensing*'s "special permission and assistance"—"federal law preempts any state tort law duty purporting to require those changes." Mem. Supp. Defs.' Mot. Summ. J. 8. In sum, the defendants argue that impossibility preemption "prohibits the states from ordering a manufacturer to make changes that the Food and Drug Administration would have the discretion to refuse." *Id.* at 1.

This spin on impossibility preemption would destroy state tort liability for any product subject to even the least rigorous federal regulatory scheme. As discussed below, Congress, the Supreme Court, and common sense counsel against such a result.

IV. Discussion

Labels aside, the core of any preemption analysis is whether state law undermines the effectiveness of federal legislation. Here, I am presented with a case in which state law requires a product to be reasonably safe and federal law requires such products be cleared prior to market on independent grounds. *Compare Morningstar v. Black & Decker Mfg. Co.*, 253 S.E. 2d 666, 683 (W. Va. 1979) ("[T]he general test for establishing strict liability in tort is whether the involved product is defective in the sense that it is not reasonably safe . . . ."), *with Lohr*, 518 U.S. at 493

("[T]he 510(k) process is focused on *equivalence*, not safety." (citation omitted)). The state safety requirement does nothing to undermine or interfere with the federal law because the federal law does not make specific demands on safety. State law does not pose an obstacle to, frustrate the purpose of, undermine, interfere with, impede, or otherwise make it impossible to comply with federal law.

A preemption inquiry is not logically triggered unless state law actually poses some impediment to federal law. The defendants' preemption argument does not pass this basic test. The attempt to cloak a preemption defense in terms of impossibility and cast it as a question of first impression is a red herring. The fact that a medical device would, in the course of its life cycle, come into contact with a state safety requirement and an unrelated federal clearance process is irrelevant for preemption purposes. Contact is not conflict. The defendants' definition of impossibility would find preemption notwithstanding the absence of any state interference with federal law, a rule without basis in the Supremacy Clause.

Determining the actual contours of a conflict is certainly a challenge where the court must divine the meaning and purpose of both federal and state law. Here, my task is made easy because the Supreme Court has already examined the purpose of the federal law at issue and determined that Congress did not intend to preempt state law design defect claims cleared through the 510(k) process. *See Lohr*, 518 U.S. at 494. While express preemption claims were at issue in *Lohr*, the analysis also supports finding against preemption under implied preemption principles. The defendants implore the court to ignore *Lohr*. But because the touchstone of *any* preemption analysis is the intent of Congress, *Lohr*'s discussion of Congress' purpose in enacting the 510(k) process is fundamentally relevant to, and ultimately dispositive of, our implied impossibility

preemption analysis.[1] A claim of impossibility preemption is demanding, and the defendants fail to meet its demands.

A. Presumption Against Preemption

The Supreme Court employs a presumption against preemption, particularly when Congress has legislated in a field which the States have traditionally occupied. *Wyeth*, 555 U.S. at 565. In the instant case, at issue is West Virginia tort law's requirement that a product be "reasonably safe." *Morningstar*, 253 S.E.2d at 683. Because the health and safety of citizens are "'primarily, and historically, . . . matter[s] of local concern,' the 'States traditionally have had great latitude under their police powers to legislate as to the protection of the lives, limbs, health, comfort, and quiet of all persons.'" *Lohr*, 518 U.S. at 475 (alterations in original) (citation omitted) (quoting *Hillsborough Cty. v. Automated Med. Lab., Inc*., 471 U.S. 707, 719 (1985); *Metro. Life Ins. v. Massachusetts*, 471 U.S. 724, 756 (1985)). Thus, we have the quintessential example of Congress legislating in a field historically occupied by state police powers and must begin with the assumption that such powers were not to be superseded by a federal law "unless that was the clear and manifest purpose of Congress." *Wyeth*, 555 U.S. at 565 (relying on *Lohr*, 518 U.S. at 485; *Rice v. Santa Fe*, 331 U.S. at 230). As discussed below, the defendants have not demonstrated that it was the clear and manifest purpose of Congress to immunize medical device-makers from state tort liability, and so have not overcome the presumption against preemption.

B. Intent of Congress

The Supreme Court has repeatedly indicated that the touchstone of *every* preemption

[1] This court cannot ignore the Supreme Court's determinations that are directly applicable to this case. *See United States v. Danielczyk*, 683 F.3d 611, 615 (4th Cir. 2012) ("[L]ower courts should not conclude that the Supreme Court's 'more recent cases have, by implication, overruled [its] earlier precedent.'" (second alteration in original) (quoting *Agostini v. Felton*, 521 U.S. 203, 237 (1997))).

analysis is the intent of Congress.[2] *E.g.*, *Wyeth*, 555 U.S. at 565. In this case, the presence of an express preemption provision in the MDA is important evidence of Congress' intent.[3] *See CSX Transp.*, 507 U.S. at 664 (noting that an express pre-emption clause "necessarily contains the best evidence of Congress' pre-emptive intent."). Even *Bartlett*, on which the defendants rely, discusses the importance of an express preemption clause as evidence of congressional intent. *Bartlett*, 133 S. Ct. at 2480 ("[T]he FDCA's treatment of prescription drugs includes neither an express pre-emption clause . . . nor an express non-pre-emption clause . . . . In the absence of that sort of 'explicit' expression of congressional intent, we are left to divine Congress' will from the duties the statute imposes."). In *Lohr*, the court held that the scope of the MDA's express provision (i.e., 21 U.S.C. § 360k(a)) did not extend to state law design defect claims for products cleared through the 510(k) process. At a minimum, this is consistent with an inference that Congress did not intend to preempt state common law claims outside the scope of the express provision. But *Lohr* goes even further and examines Congress' purpose in enacting the 510(k) provision specifically.

The Court in *Lohr* unquestionably determined Congress did not intend for the expedited 510(k) process to supplant state tort common law regarding design defects. *Lohr*, 518 U.S. at 494. Congress enacted the MDA in 1976, which established the "rigorous" premarket approval

[2] Despite relying on *Wyeth*'s impossibility preemption holdings, the defendants make no mention of Congress' intent in their arguments or proposed analysis.

[3] Express preemption clauses may imply a lack of intent to preempt matters outside their scope. *Freightliner Corp. v. Myrick*, 514 U.S. 280, 288 (1995); *Cipollone v. Liggett Grp., Inc.*, 505 U.S. 504, 517 (1992) ("Congress' enactment of a provision defining the pre-emptive reach of a statute implies that matters beyond that reach are not pre-empted."). Nevertheless, the presence of an express preemption clause does not categorically extinguish the possibility that the matter could be impliedly preempted. *See, e.g.*, *Freightliner*, 514 U.S. at 288 ("The fact that an express definition of the pre-emptive reach of a statute 'implies'–*i.e.*, supports a reasonable inference–that Congress did not intend to pre-empt other matters does not mean that the express clause entirely forecloses any possibility of implied pre-emption."); *see also, e.g.*, *Arizona*, 132 S. Ct. at 2504 ("[T]he existence of an 'express pre-emption provisio[n] does *not* bar the ordinary working of conflict pre-emption principles . . . .'"(quoting *Geier v. Am. Honda Motor Co.*, 529 U.S. 861, 869–70 (2000))).

("PMA") process, as well as an "exception" to this process known as 510(k) notification. *Id.* at 476–78. The PMA process required manufacturers of certain devices to "submit detailed information regarding the safety and efficacy of their devices, which the FDA then reviews, spending an average of 1,200 hours on each submission." *Id.* at 477. By contrast, the 510(k) process imposes a "limited form of review" through which the FDA determines whether the "device is substantially equivalent to a pre-existing device." *Id.* at 478. The 510(k) provision imposes no duty on medical device makers to design their products in a particular manner. *See Lohr*, 518 U.S. at 493 (explaining that the FDA, in its 510(k) process "did not require Medtronic's pacemaker to take any particular form for any particular reason"). The purpose of allowing devices to avoid the PMA process and use 510(k) instead was, as described by the Supreme Court in *Lohr*, to prevent manufacturers of devices already on the market, and therefore not immediately subject to the new premarket approval requirements, "from monopolizing the market while new devices cleared the PMA hurdle, and to ensure that improvements to existing devices can be rapidly introduced into the market." *Id.* at 478. The Court explained that Congress did not intend for the 510(k) exemption to preempt state law design defect claims:

> There is no suggestion in either the statutory scheme or the legislative history that the §510(k) exemption process was intended to do anything other than maintain the status quo with respect to the marketing of existing medical devices and their substantial equivalents. That status quo included the possibility that the manufacturer of the device would have to defend itself against state-law claims of negligent design.

Id. at 494. This assessment of Congress' purpose is directly applicable to the instant case.

Nonetheless, Ethicon claims federal preemption is triggered wherever the FDA "would have the discretion to refuse" a change to a product. Mem. Supp. Defs' Mot. Summ. J. 1. Such a rule misconstrues *Mensing* and is flatly inconsistent with the holding of *Wyeth*, in which the FDA's

discretion to refuse a brand-name drug's labeling changes was *not* dispositive. *Wyeth*, 555 U.S. at 571 ("Of course, the FDA retains authority to reject labeling changes . . . . But absent clear evidence that the FDA would not have approved a change to Phenergan's label, we will not conclude that it was impossible for Wyeth to comply with both federal and state requirements.").

The impossibility in *Mensing* arose from the unique "duty of sameness" imposed on generic drugs, which has no corollary in the medical device context. *See Mensing*, 131 S. Ct. at 2576, 2578 (finding impossibility because "[f]ederal law . . . demanded that generic drug labels be the same at all times as the corresponding brand-name drug labels"). In an attempt to expand the traditional bounds of impossibility preemption, the defendants rely heavily on *Mensing*'s "special permission and assistance" language.[4] *See, e.g.*, Mem. Supp. Defs.'s Mot. Summ. J. 4–6, 8; *see also Mensing*, 131 S. Ct. at 2581. This reliance is misplaced. The Supreme Court has cited *Mensing* in two subsequent majority opinions, but has nowhere referred to "special permission and assistance" in a preemption analysis. In *Wos v. E.M.A*, 133 S. Ct. 1391 (2013), the Court cites *Mensing* for the proposition that "[w]here state and federal law 'directly conflict,' state law must give way." *Wos*, 133 S. Ct. at 1398 (alteration in original). Even in *Bartlett*, a generic drug preemption case which purports to apply *Mensing*, the Court declines to use *Mensing*'s specific articulation of impossibility. *Bartlett*, 133 S. Ct. at 2473 (explaining that state law is "impliedly pre-empted where it is 'impossible for a private party to comply with both state and federal requirements'" (quoting *English v. Gen. Elec. Co.*, 496 U.S. 72, 79 (1990)). Instead, *Mensing* is

[4] Impossibility preemption has traditionally been defined narrowly and applied stringently. *See, e.g.*, *Fla. Lime & Avocado*, 73 U.S. at 142–43 (requiring preemption when "compliance with both federal and state regulations is a physical impossibility" and finding no preemption absent an "inevitable collision between the two schemes of regulation"); Daniel J. Meltzer, *Preemption and Textualism*, 112 Mich. L. Rev. 1, 8 (2013) (describing as "rare" those situations in which it is impossible to comply with both state and federal requirements); Ernst A. Young, *The Ordinary Diet of the Law: The Presumption Against Preemption in the Roberts Court*, 2011 Sup. Ct. Rev. 253, 273 ("Traditionally, the Court has defined 'impossibility' very narrowly . . . .").

used mainly for its recognition that "federal law prohibits generic drug manufacturers from independently changing their drugs' labels." *Bartlett*, 133 S.Ct. at 2470.

The defendants' focus demonstrates their misunderstanding of the nature of the impossibility found in *Mensing*, which was the direct conflict between the "state-law duty to change the label and the[] federal law duty to keep the label the same." *Mensing*, 131 S. Ct. at 2578. In *Mensing*, there was no official regulatory process by which a generic could change its label, so the generic manufacturer was "barred" from taking the action state law required. *Id.* at 2581. This is completely different from the defendants' situation in the instant case. Unlike the law imposing the duty of sameness for generics, there is no federal law prohibiting design changes to medical devices, particularly changes representing advances in safety. To the contrary, one of the purposes of the 510(k) exemption was "to ensure that improvements to existing devices can be rapidly introduced into the market." *Lohr*, 518 U.S. at 478. The law simply requires that manufacturers making a "significant change" submit another 510(k) notification, which the FDA will clear if it determines the device is substantially equivalent to a device already on the market. 21 C.F.R. § 807.81(a)(3) (2007). Again, this substantial equivalence determination does not directly conflict with the state law requirement that a product be reasonably safe.

V. Conclusion

In light of Congress' purpose in enacting the 510(k) provision and the absence of any actual conflict between state and federal law, I do not find implied impossibility preemption in this case. Accordingly, the defendants' Motion for Summary Judgement [ECF No. 128] is **DENIED**. The court **DIRECTS** the Clerk to send a copy of this Order to counsel of record and any unrepresented party. The court further **DIRECTS** the Clerk to post a copy of this published opinion on the

court's website, www.wvsd.uscourts.gov.

ENTER: December 2, 2015

JOSEPH R. GOODWIN
UNITED STATES DISTRICT JUDGE